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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,377	07/18/2003	Thomas J. Jentsch	59572(46865)	9926

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Edwards & Angell, LLP
Intellectual Property Practice Group
P.O. Box 55874
Boston, MA 02205

EXAMINER

HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,377

Applicant(s)

JENTSCH, THOMAS J.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 26-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

This Application, filed July 18, 2003, is a continuation of PCT/DK/02/00038, filed January 17, 2002. This Application claims benefit to German (DE) Patent Application 101 02 977.2 filed on January 23, 2001.

A preliminary Amendment was filed on July 18, 2003. Claims 1-25 have been cancelled and new claims (26-41) have been added.

Claims 26-41 are pending.

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 26-30, drawn to a cell line which does not express or expresses to a reduced extent one or more chloride channels, classified in class 435, subclass 325.
- II. Claim 31, drawn to the use of a genetically modified, non-human mammal, germ cells, and somatic cells which contain nucleic acids sequences which code for a protein consisting of chloride channels, classified in class 800, subclass 3.
- III. Claims 32-37, drawn to the use of a cell line for the identification and testing of substances suitable for inhibiting chloride channels, classified in class 435, subclass 325.
- IV. Claims 38-40, drawn to a process for identifying and testing substances which are suitable for inhibiting one or more chloride channels, classified in class 424, subclass 9.1, or class 536, subclass 23.1.

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- V. Claim 41, drawn to the use of substances which completely or partly inhibit ClC-7, classified in class 424, subclass 9.1 or class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is to a cell line that has low to no expression of one or more chloride channels. Invention II is to the use of a genetically modified, non-human mammal, germ cells, and somatic cells which contain nucleic acids sequences which code for a protein consisting of chloride channels. Invention I does not depend on Invention II to function and vice versa.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is to a cell line that has low to no expression of one or more chloride channels. Invention III is to the use of a cell line for the identification and testing of substances suitable for inhibiting chloride channels. Invention I does not depend on Invention III to function and vice versa.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). Invention I is to a cell line that has low to no expression of one or more chloride channels. Invention IV is to a process for identifying and testing substances which are suitable for inhibiting one or more chloride channels. Invention I does not depend on Invention IV to function and vice versa.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is to a cell line that has low to no expression of one or more chloride channels. Invention V is the use of substances which completely or partly inhibit ClC-7. Invention I does not depend on Invention V to function and vice versa.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is to the use of a genetically modified, non-human mammal, germ cells, and somatic cells which contain nucleic acids sequences which code for a protein consisting of chloride channels. Invention III is to the use of a cell line for the identification and testing of substances suitable for inhibiting chloride channels. Invention II does not depend on Invention III to function and vice versa.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is to the use of a genetically modified, non-human mammal, germ cells, and somatic cells which contain nucleic acids sequences which code for a protein consisting of chloride channels. Invention IV is to a process for identifying and testing substances which are suitable for inhibiting one or more chloride channels. Invention II does not depend on Invention IV to function and vice versa.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is to the use of a genetically modified, non-human mammal, germ cells, and somatic cells which contain nucleic acids sequences which code for a protein consisting of chloride channels. Invention V is to the use of substances which completely or partly inhibit CIC-7. Invention II does not depend on Invention V to function and vice versa.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention III is to the use of a cell line for the identification and testing of substances suitable for inhibiting chloride channels. Invention IV is to a process for identifying and testing substances which are suitable for inhibiting one or more chloride channels. Invention III does not depend on Invention IV to function and vice versa.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention III is to the use of a cell line for the identification and testing of substances suitable for inhibiting chloride channels. Invention V is to the use of substances which completely or partly inhibit CIC-7. Invention III does not depend on Invention V to function and vice versa.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention IV is to a process for identifying and testing substances which are suitable for inhibiting chloride channels. Invention V is to the use of substances which completely or partly inhibit CIC-7. Invention IV does not depend on Invention V to function and vice versa. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and the search required for one Invention is not required for another Invention, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

Joe Winters
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